



HW

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| | | |
|---|------------------------|-------------------------------|
| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 10/622,272 |
| | Filing Date | July 17, 2003 |
| | First Named Inventor | Modak et al. |
| | Art Unit | (Not Yet Assigned) |
| | Examiner Name | (Not Yet Assigned) |
| Total Number of Pages in This Submission | Attorney Docket Number | 35008 PCT USA-A (070050.2429) |

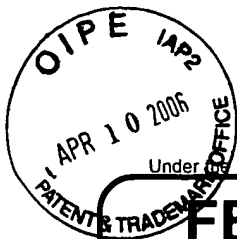
| ENCLOSURES (Check all that apply) | | |
|---|---|--|
| <input checked="" type="checkbox"/> Fee Transmittal Form | <input type="checkbox"/> Drawing(s) | <input type="checkbox"/> After Allowance Communication to TC |
| <input type="checkbox"/> Fee Attached | <input type="checkbox"/> Licensing-related Papers | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences |
| <input type="checkbox"/> Amendment/Reply | <input type="checkbox"/> Petition | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final | <input type="checkbox"/> Petition to Convert to a Provisional Application | <input type="checkbox"/> Proprietary Information |
| <input type="checkbox"/> Affidavits/declaration(s) | <input type="checkbox"/> Power of Attorney, Revocation | <input type="checkbox"/> Status Letter |
| <input type="checkbox"/> Extension of Time Request | <input type="checkbox"/> Change of Correspondence Address | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): |
| <input type="checkbox"/> Express Abandonment Request | <input type="checkbox"/> Terminal Disclaimer | Supplemental Information Disclosure Statement; Form PTO-1449; Copies of Six (6) References; Return Receipt Postcard. |
| <input checked="" type="checkbox"/> Information Disclosure Statement | <input type="checkbox"/> Request for Refund | |
| <input type="checkbox"/> Certified Copy of Priority Document(s) | <input type="checkbox"/> CD, Number of CD(s) _____ | |
| <input type="checkbox"/> Reply to Missing Parts/Incomplete Application | <input type="checkbox"/> Landscape Table on CD | |
| <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | Remarks | |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | | | |
|--|-----------------|--------------|--------|
| Firm Name | Baker Botts LLP | Customer No. | 21003 |
| Signature | | | |
| Printed name | Lisa B. Kole | | |
| Date | 04/07/2006 | Reg. No. | 35,225 |

| CERTIFICATE OF TRANSMISSION/MAILING | |
|---|--------------|
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: | |
| Signature | |
| Typed or printed name | Lisa B. Kole |
| Date | 04/07/2006 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/17 (10-04)

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FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 0

Complete if Known

| | |
|----------------------|-----------------------------|
| Application Number | 10/662,272 |
| Filing Date | July 17, 2003 |
| First Named Inventor | Modak et al. |
| Examiner Name | (Not Yet Assigned) |
| Art Unit | (Not Yet Assigned) |
| Attorney Docket No. | 35008 PCT USA-A 070050.2429 |

METHOD OF PAYMENT (check all that apply)☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit Account Number
Deposit Account Name

02-4377

Baker Botts L.L.P.

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

| Large Entity Fee Code | Small Entity Fee Code | Fee Description | Fee Paid |
|-----------------------|-----------------------|------------------------|----------|
| 1001 | 2001 | Utility filing fee | |
| 1002 | 2002 | Design filing fee | |
| 1003 | 2003 | Plant filing fee | |
| 1004 | 2004 | Reissue filing fee | |
| 1005 | 2005 | Provisional filing fee | |
| SUBTOTAL (1) | | | (\$) 0 |

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| Total Claims | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|----------|
| Independent Claims | -20 = | X | =0 |
| Multiple Dependent | -3 = | X | =0 |

| Large Entity Fee Code | Small Entity Fee Code | Fee Description |
|-----------------------|-----------------------|--|
| 1202 | 2202 | Claims in excess of 20 |
| 1201 | 2201 | Independent claims in excess of 3 |
| 1203 | 2203 | Multiple dependent claim, if not paid |
| 1204 | 2204 | ** Reissue independent claims over original patent |
| 1205 | 2205 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) (\$) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

| Large Entity Fee Code | Small Entity Fee Code | Fee Description | Fee Paid |
|-----------------------|-----------------------|--|----------|
| 1051 | 2051 | Surcharge - late filing fee or oath | |
| 1052 | 2052 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 | 1053 | Non-English specification | |
| 1812 | 1812 | For filing a request for <i>ex parte</i> reexamination | |
| 1804 | 1804 | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1805 | Requesting publication of SIR after Examiner action | |
| 1251 | 2251 | Extension for reply within first month | |
| 1252 | 2252 | Extension for reply within second month | |
| 1253 | 2253 | Extension for reply within third month | |
| 1254 | 2254 | Extension for reply within fourth month | |
| 1255 | 2255 | Extension for reply within fifth month | |
| 1401 | 2401 | Notice of Appeal | |
| 1402 | 2402 | Filing a brief in support of an appeal | |
| 1403 | 2403 | Request for oral hearing | |
| 1451 | 1451 | Petition to institute a public use proceeding | |
| 1452 | 2452 | Petition to revive - unavoidable | |
| 1453 | 2453 | Petition to revive - unintentional | |
| 1501 | 2501 | Utility issue fee (or reissue) | |
| 1502 | 2502 | Design issue fee | |
| 1503 | 2503 | Plant issue fee | |
| 1460 | 1460 | Petitions to the Commissioner | |
| 1807 | 1807 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 1806 | Submission of Information Disclosure Stmt | X |
| 8021 | 8021 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 2809 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 2810 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 | 2801 | Request for Continued Examination (RCE) | |
| 1802 | 1802 | Request for expedited examination of a design application | |

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 0

SUBMITTED BY

(Complete (if applicable))

| | | | | | |
|-------------------|--------------|-----------------------------------|---------------|-----------|--------------|
| Name (Print/Type) | Lisa B. Kole | Registration No. (Attorney/Agent) | 35,225 | Telephone | 212 408-2628 |
| Signature | | Date | April 7, 2006 | | |

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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35008-PCT-USA-A (070050.2429)
COL IR: 1583 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Modak et al. Costumer No.: 21003
Serial No. : 10/622,272 Examiner: Not Yet
Assigned
Filed : July 17, 2003 Group Art Unit: Not Yet Assigned
For : ZINC SALT COMPOSITIONS FOR THE PREVENTION OF
DERMAL AND MUCOSAL IRRITATION

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being
deposited with the United States Postal
Service as first class mail in an envelope
addressed to: Commissioner for Patents,
P.O. Box 1450, Alexandria, VA 22313-
1450.

April 7, 2006
Date of Deposit

Lisa B. Kole
Attorney Name
[Signature]
Signature

35,255
Patent Reg. No.
April 7, 2006
Date of Signature

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants respectfully request that the documents listed below in reverse chronological order and on the accompanying PTO 1449 be considered by the Examiner and made of record in the above-referenced application. Full text copies of non-patent publications, foreign Patent documents and

foreign published Patent Applications listed herein are enclosed in the accompanying volume of references. Applicants have not enclosed copies of issued U.S. Patents or published U.S. Patent Applications as their submission is not required under 37 C.F.R. § 1.98(a)(2)(ii). Applicants will provide copies of any issued U.S. Patent or published U.S. Patent Application disclosed in this Information Disclosure Statement should the Examiner so require. References are numbered 41-48 in continuation with references 1-40 cited in the prior Information Disclosure Statement filed November 3, 2004.

41. Modak et al., 2005, A topical cream containing a zinc gel (allergy guard) as a prophylactic against latex glove-related contact dermatitis. *Dermatitis*. 16(1):22-7.
42. Hoang et al., U.S. Patent No. 6,723,689 issued April 20, 2004 for "Emollient Alcohol Skin Disinfecting Formulation."
43. Modak et al., International Patent Application No. PCT/US03/03896, published on August 14, 2003, as WO 03/066001 for "Zinc salt compositions for the prevention of mucosal irritation from spermicides and microbicides."
44. Kelly, U.S. Patent No. 6,321,750 issued November 27, 2001 for "Condom lubricants with zinc salts as anti-viral additives."
45. Modak SM, et al., A Topical Zinc Gluconate Gel Composition for the Prevention of latex/Starch Glove Related Allergic Reactions: Pilot Study in Volunteers. In: Programs and Abstracts of the 37th Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto: 1997; American Society for Microbiology Washington DC. Abstract J -52.

46. Goodman and Gilman's The Pharmacological Basis of Therapeutics (Goodman Gilman A, Rall TW, Nies AS, Taylor P, ed. (Pergamon Press; Elmsford, N.Y.: 1990).
47. Bush et al., 1986, "Pig skin as test substrate for evaluating topical antimicrobial activity" J Clin Microbiol 24:343-348.
48. Meyer et al., 1978, "The skin of domestic mammals as a model for the human skin, with special reference to the domestic pig." Curr. Problem Dermatol 7:39-52.

Identification of the listed documents is not to be construed as an admission of the applicants or attorneys for applicants that such citations are available as "prior art" against the subject application. If the Examiner applies the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

Applicants believe there is no fee required for this timely submission. However, if any fee is required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted,
BAKER BOTTS L.L.P.

A handwritten signature in black ink, appearing to read 'LBK', written over a horizontal line.

Lisa B. Kole
PTO Reg. No. 35,225

30 Rockefeller Plaza
44th Floor
New York, NY 10012-4498

Attorney for Applicants
(212) 408 2628

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark Office

Atty: Docket No.
A35008-PCT-USA-A
(070050.2429)

Serial No.
10/622,272

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

(Use several sheets if necessary)

Applicants
Modak et al.

Filing Date
July 17, 2003

Group Art Unit
Not Yet Assigned

U.S. PATENT DOCUMENTS

| *Exam. Init. | Document No. | Date | Name | Class | Subclass | Filing Date if Appropriate |
|-----------------|---------------|------------|--------------|-------|----------|-------------------------------|
| 42 | 6 7 2 3 6 8 9 | 4/20/04 | Hoang et al. | | | |
| 44 | 6 3 2 1 7 5 0 | 11/27,2001 | Kelly | | | |
| | | | | | | |

FOREIGN PATENT DOCUMENT

| Document No. | Date | Country | Class | SubClass | Translator Yes No |
|-------------------|----------|---------|-------|----------|----------------------|
| 43. 0 3 0 3 8 9 6 | 08/14/03 | WIPO | | | |

OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)

| | |
|-----|---|
| 41. | Modak et al., 2005, A topical cream containing a zinc gel (allergy guard) as a prophylactic against latex glove-related contact dermatitis. Dermatitis. 16(1):22-7. |
| 45 | Modak SM, et al., A Topical Zinc Gluconate Gel Composition for the Prevention of latex/Starch Glove Related Allergic Reactions: Pilot Study in Volunteers. In: Programs and Abstracts of the 37 th Interscience Conference on Antimicrobial Agents and Chemotherapy, Toronto: 1997; American Society for Microbiology Washington DC. Abstract J -52. |
| 46. | Goodman and Gilman's The Pharmacological Basis of Therapeutics (Goodman Gilman A, Rall TW, Nies AS, Taylor P, ed. (Pergamon Press; Elmsford, N.Y.: 1990). |
| 47 | Bush et al., 1986, "Pig skin as test substrate for evaluating topical antimicrobial activity" J Clin Microbiol 24:343-348. |
| 48. | Meyer et al., 1978, "The skin of domestic mammals as a model for the human skin, with special reference to the domestic pig." Curr. Problem Dermatol 7:39-52. |

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

544777